Xhance Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
5/1/2023

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Xhance® (fluticasone 93 mcg/actuation) Nasal spray	Treatment of nasal polyps in patients 18 years of age or older		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Chronic Rhinosinusitis with Nasal Polyposis	Chronic rhinosinusitis with nasal polyposis (CRSwNP) is an inflammatory condition affecting the paranasal sinuses that is diagnosed by the presence of both subjective and objective evidence of chronic sinonasal inflammation. Hallmarks of the disease consist of at least two out of four cardinal symptoms (i.e., facial pain/pressure, hyposmia/anosmia, nasal drainage, and nasal obstruction) for at least 12 consecutive weeks. The objective evidence of sinonasal inflammation and nasal polyps is needed to confirm the diagnosis may be obtained by physical examination (anterior rhinoscopy, nasal endoscopy) or from sinus computed tomography (CT).(2-4) The exact cause of CRSwNP is unknown, but biopsies of nasal polyps have shown elevated levels of eosinophils.(2) First line therapy for CRSwNP consists of nasal saline irrigation in combination with intranasal corticosteroids.(2-4) The American Academy of Family Physicians notes that no one intranasal corticosteroid is superior to another or that increased dosing provides greater effectiveness. The American Academy of Otolaryngology recommends a short course of oral corticosteroids if no response is seen with intranasal corticosteroids after 3-months of appropriate use.(4) Short courses of oral corticosteroids (up to three weeks) can improve sinonasal symptoms and endoscopic findings. Surgical intervention may be required in patients who fail medical management.(2,3)
Efficacy	The efficacy of Xhance was evaluated in two randomized, double-blind, parallel group, multicenter, placebo-controlled, dose-ranging trials in adults 18 years and older with nasal polyps and associated moderate to severe nasal congestion (NCT 01622569, NCT 01624662). The two trials included a total of 646 subjects. Subjects were randomized 1:1:1:1 to receive 93 mcg, 186 mcg, or 372 mcg twice daily or placebo for a period of 16 weeks. At baseline 90.6% of patients reported previous use of a topical steroid nasal spray for the treatment of nasal polyps. The co-primary efficacy endpoints were 1) change from baseline to Week 4 in nasal congestion/obstruction averaged over the preceding 7 days of treatment and 2) change from baseline to Week 16 in bilateral polyp grade. Nasal congestion was rated by the patient on a 0 to 3 categorical severity scale at the time immediately prior to the next dose (instantaneous). Polyp grade was determined by the clinician using nasal endoscopy.

	Polyps on each side of the nose were graded on a categorical scale. Efficacy was demonstrated for both Xhance 186-mcg twice daily and Xhance 372-mcg twice daily. Onset of action, evaluated by determining the starting period that the treatment effect of Xhance on daily instantaneous AM congestion score started to achieve statistical significance in comparison to placebo and roughly maintained thereafter, was generally observed within 2 weeks for both Xhance doses.(1)
Safety	Xhance is contraindicated in patients with a hypersensitivity to any ingredient.(1)

REFERENCES

Number	Reference
1	Xhance prescribing information. OptiNose US, Inc. April 2021.
2	Stevens, W. W., Schleimer, R. P., & Kern, R. C. (2016). Chronic Rhinosinusitis with Nasal Polyps. The journal of allergy and clinical immunology. In practice, 4(4), 565–572. doi:10.1016/j.jaip.2016.04.012.
3	Sedaghat, A. R. (2017). Chronic Rhinosinusitis. American Family Physicians, 96(8), 500-506.
4	Rosenfeld, R.M., Piccirillo, J.F., Chandrasekhar, S.S., Itzhak, B., Kumar, K. A., Kramper, M., Orlandi, R. R., Palmer, J. N., Patel, Z. M., Peters, A., Walsh, S. A., Corrigan, M. D. (2015). Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. 2015; 152(2 suppl): S1-S39.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Preferred Status	Effective Date
Xhance	Fluticasone Propionate Nasal Exhaler Susp 93 MCG/ACT	93 MCG/ACT	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date
Xhance	Fluticasone Propionate Nasal Exhaler Susp 93 MCG/ACT	93 MCG/ACT	2	BOTTS	30	Days				

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xhance	Fluticasone Propionate Nasal Exhaler Susp 93 MCG/ACT	93 MCG/ACT	Commercial ; HIM ; ResultsRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xhance	Fluticasone Propionate Nasal Exhaler Susp 93 MCG/ACT	93 MCG/ACT	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of nasal polyps **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response after 90 days of therapy with ONE generic OR OTC intranasal corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with generic or OTC intranasal corticosteroids that is not expected to occur with the requested agent **OR**

Module	Clinical Criteria for Approval
	C. The patient has an FDA labeled contraindication to ALL generic AND OTC intranasal corticosteroids that is not expected to occur with the requested agent **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months Note: Quantity Limit applies, see Quantity Limit criteria section below. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decreased nasal congestion, pain, pressure, rhinorrhea, nasal polyp size; increased sense of smell) **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months Note: Quantity Limit applies, see Quantity Limit criteria section below.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months